

REMARKS

FEB 20 2001

Claims 19, 21, 25, 27, 29, 33-35, and 41-57 are under examination and stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. The claims were acknowledged to be free of the prior art. Claims 50 and 51 are canceled. Claims 35 and 55 are amended to clarify that the protein is deposited in the white of the egg (which is "on the yolk"). Reconsideration of the rejection and allowance of claims 19, 21, 25, 27, 29, 33-35, 41-49 and 52-57 are requested.

Rejection Under 35 U.S.C. §112

All pending claims stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The Examiner acknowledges that the specification teaches the production of chimeric chickens, but states that the specification fails to show even a single transgenic founder obtained from chimeric chickens, capable of producing a transgenic progeny. The Examiner further states that the art at the time of filing teaches that the making of transgenic birds is highly unpredictable and that the specification fails to disclose a single working example of any transgenic bird, as well as failing to show the expression of any exogenous protein in the tubular gland cells of oviduct or magnum tissue. Secondly, the Examiner objects to claim 50, which reads on post-translational modification of the proteins deposited in an avian egg, for failure to disclose the enzymes required for the modification. Claims 50 and 51 have been canceled, with reservation for presentation in a derivative application, in order to facilitate prosecution of the primary claims.

This rejection is respectfully traversed in view of the arguments presented below and the accompanying Declaration under 37 CFR 1.132 of Dr. Jeffrey Rapp attesting to the successful production of transgenic birds expressing exogenous proteins in accord with the teachings of the instant application. At the interview of December 19, 2000 between Examiners Kaushal and Clark and applicants' representative, Dr. Judy Jarecki-Black, the enablement issue was discussed and it was agreed that applicants would present declaratory evidence of the expression of transgenic products in eggs. The Declaration of Dr. Rapp is presented to address this issue. As detailed in the Declaration, following the procedures of the instant application, G<sub>0</sub>, G<sub>1</sub>, and G<sub>2</sub> transgenic birds have been produced and detectable levels of exogenous proteins have been identified in serum and in egg white. The procedure has been successfully practiced to express four exogenous proteins in the serum of transgenic birds: human interferon  $\alpha$ -2b (hIFN), human erythropoietin (hEPO), human granulocyte macrophage colony stimulating factor (hGM-CSF), and  $\beta$ -lactamase ( $\beta$ -lac). To date, both hIFN and  $\beta$ -lac have been found in egg white material of G<sub>2</sub> hens. It is expected that similar results will be obtained for hEPO and hGM-CSF when those experiments are completed.

Applicants encourage the Examiner to accord the Declaration of Rapp full credit as demonstrating the enablement of the invention claimed in this application.

Applicants submit that the Examiner is relying upon an inappropriate and unsanctioned standard of enablement, contrary to the direction of the Board of Patent Appeals and the Court of Appeals for the Federal Circuit, as summarized in M.P.E.P. § 2164. The analysis of whether a claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation (M.P.E.P. § 2164.01).

M.P.E.P. § 2164.02 states that compliance with the enablement requirement does not turn on whether an example is disclosed. There is no decision which stands for the proposition relied upon by the Examiner in this application that allowable subject matter is limited only to working examples. In fact, the Declaration of Dr. Rapp convincingly demonstrates that one skilled in the art following the teachings of the instant application could produce the claimed invention without undue experimentation.

Further, as stated in M.P.E.P. § 2164.08, the only relevant concern should be whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. How a teaching is set forth, by specific example or broad terminology, is not important. According to *In re Bowen*, 181 USPQ 48 (CCPA 1974) the minimal requirement is for the Examiner to give reasons for the uncertainty of the enablement. This standard is applicable even when there is no evidence in the record of operability without undue experimentation beyond the disclosed embodiments (M.P.E.P. §2164.04). Applicants submit that the current application satisfies the *Wands* criteria. Briefly reviewing each criteria:

1. The quantity of experimentation necessary is limited in view of the teachings of the application.
2. The amount of guidance presented is sufficient. See the Declaration of Rapp.
3. Applicants have provided working and prophetic examples of their invention and demonstrated expression of four different proteins.
4. The nature of the invention is such that the Applicants have achieved a goal which, despite long felt need and the efforts of others, had heretofore been unacheivable.
5. The prior art is replete with failed attempts by others to prepare a transgenic avian.
6. The relative skill of those in the art is high, so that it would be trivial for a skilled artisan, once advised of this invention, to produce transgenic chickens.
7. The claims are limited to transgenic birds expressing an exogenous gene.

Conclusion

Applicants submit that the disclosure meets the *Wands* criteria and therefore is enabling. Reconsideration and allowance of claims 19, 21, 25, 27, 29, 33-35, 41-49, and 52-57 in view of the foregoing remarks and the Declaration of Dr. Jeffrey Rapp are earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'William Schmonsees', with a long horizontal flourish extending to the right.

William Schmonsees  
Attorney for Applicants  
Reg. No. 31,796

Heller Ehrman White & McAuliffe  
275 Middlefield Road  
Menlo Park, CA 94025-3506  
(650) 324-7041  
Date: February 8, 2001